

with the applicable rules. Because the foregoing claims do not introduce new matter, applicants request that the examiner enter them.

Following entry of this amendment claims 1-20 are pending.

### **Specification**

The specification has been amended to correct a typographical error. Support for this amendment can be found in the Amendment Filed in Response to Notice Under §§ 1.821-825 file January 20, 2000.

### **Rejections under 35 U.S.C. § 112, second paragraph**

Claims 2 and 4-8 are rejected for failing to specifically claim the subject matter of the invention.

The rejection contends that claim 2 is indefinite because the term "having" is not legally defined. According to *Regent of the Univ. of Cal. V. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997), having is a transitional phrase that in terms of a cDNA allows for the inclusion of other moieties. For this reason alone, the rejection is without basis and should be withdrawn. In any event applicants do not believe that rejection pertains to current claim 2. For this reason as well, the rejection is unsubstantiated and should be withdrawn.

Similarly, the rejection states that claim 4 is incomplete since it lacks a step that refers to the method stated in the preamble. Present claim 4 recites "(a) method of screening for a compound with the ability to inhibit expression or functionality of the CaNIK1 protein." This method includes a step for "monitoring the ability of said test substance to inhibit expression or functionality of said protein encoded by said polynucleotide in said yeast cell." Therefore, applicants do not believe that this rejection currently applies. Thus, this rejection is without merit and should be withdrawn.

Finally, the rejection states that there is no antecedent basis for the phrase "said DNA" in claim 6. Once again, applicants do not believe that this rejection pertains to current claim 6 that recites "said polynucleotide."

**Rejections under 35 U.S.C. § 102(e)**

The rejection contends that Alex anticipates claims 1-3. Enclosed with the response, applicants submit a Declaration under Rule 131 demonstrating that Alex is unavailable as prior art under section 102.

Specifically, applicants present notebook entries, Exhibits A-C, which evidence the conception of applicants' invention coupled with due diligence prior to the 102(e) date of Alex. The conception is followed by an actual reduction to practice of the invention. Since the conception of applicants' invention antedates the 102(e) date of Alex, the reference cannot be cited as art against the present application. Therefore, this rejection is without merit and should be withdrawn.

**Rejections under 35 U.S.C. § 103(a)**

Claims 4-8 are rejected as obvious over Alex in view of Timberlake.

For the reasons given above, Alex cannot be cited as art with respect to the claimed invention. Therefore, its teachings are irrelevant for the purpose of the present rejection.

Furthermore, Timberlake is insufficient to sustain a prima facie case of obviousness. Applicants teach a "method of screening for a compound with the ability to inhibit expression or functionality of the CaNIK1 protein." According to the rejection, Timberlake describes the use of a reporter gene to monitor the activity of target genes after contact with a potential antifungal compound. Since Timberlake does not describe the CaNIK1 protein or its role in pathogenesis, the artisan of ordinary skill would not have been motivated to develop applicants' invention. Moreover, "monitoring the ability of said test substance to inhibit expression or functionality" of the CaNIK1 protein is an important claim limitation Timberlake does not teach or suggest. Therefore, Timberlake is not able to sustain a prima facie case of obviousness since: (a) this reference does not provide the suggestion or motivation to modify the reference along the lines recited in claims 4-8, (b) the reference does not teach or suggest all of the limitations of the aforementioned claims. Thus, this rejection is without basis and should be withdrawn.

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### CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

Respectfully submitted,

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**Versions with Markings to Show Changes Made**

**In the Specification:**

Please amend the Specification as follows:

Please replace the paragraph on page 2, beginning at line 9 with the following rewritten paragraph:

In accomplishing these and other objects, there has been provided, according to one aspect of the present invention, an isolated polynucleotide that codes for such a protein and that hybridizes, under stringent conditions, to the polynucleotide sequence of SEQ ID No. 1, shown below in Figure 1. In a preferred embodiment, the polynucleotide has the sequence of SEQ ID No. [2] 3 (Figure 2). In another preferred embodiment, the protein displays a kinase activity.

**In the Claims:**

1. (Amended) An isolated polynucleotide that codes for a protein that is linked to phenotypic switching in *Candida albicans* and that hybridizes, under stringent conditions, to the polynucleotide sequence of SEQ ID NO.1.
2. (Amended) A polynucleotide according to claim 1, having the sequence of SEQ ID NO. [2] 3.
4. (Amended) A method of screening for a compound with the ability to inhibit expression or functionality of the CaNIK1 protein [for of screening compounds to identify pharmaceutical candidates], comprising [the steps of ](A) [providing a plurality of cells from yeast specie[s] or species] contacting a yeast cell that exhibits phenotypic switching, with a test substance [at least some of which contain ] wherein said yeast cell comprises (i) a polynucleotide according to claim 1 and (ii) a promoter that is operably linked to said polynucleotide, such that said yeast cell [plurality] produces [said] a protein encoded by said polynucleotide of claim 1; then (B) [bringing said plurality into contact with a test

substance; and (C)] monitoring [what effect, if any,] the ability of said test substance [has on the expression of said DNA segment.] to inhibit expression or functionality of said protein in said yeast cell in contact with said test substance.

5. (Amended) [A] The method according to claim 4, wherein step ([C]B) comprises monitoring the level of said protein produced in said yeast cell.

6. (Amended) [A] The method according to claim 4, wherein step ([C]B) comprises monitoring the level of mRNA encoded by said [DNA and produced by said plurality] polynucleotide in said yeast cell.

7. (Amended) [A] The method according to claim 4, wherein step ([C]B) comprises monitoring the level of kinase activity within said [plurality,] yeast cell, wherein said kinase activity typifies said protein.

8. (Amended) [A] The method according to claim 4, wherein a promoter is operably linked to a reporter gene and wherein step ([C]B) comprises monitoring the level of transcription of [the] said reporter gene in said yeast cell [after contact between said plurality and said test substance].